REMARKS

<u>I.</u> <u>Status Summary</u>

Claims 1-4 and 7-10 are pending in the subject U.S. patent application and have been examined by the United States Patent and Trademark Office (hereinafter "the Patent Office") in a Non-Final Official Action dated April 29, 2009 (hereinafter the "Non-Final Official Action").

Claims 1-4 and 7-10 have been rejected under 35 U.S.C. § 112, first paragraph, upon the contention that the specification does not enable the full scope of the claims.

Claims 1-4 and 7-10 have been rejected under 35 U.S.C. § 112, second paragraph, upon the contention that certain phrases recited in the claims are unclear.

Claims 1 and 7 have been amended. Support for the amendments can be found throughout the specification as filed, including particularly at page 3, lines 24-26; at page 4, lines 5-7; and in the Examples, particularly Example 1. As such, no new matter has been added by the amendments to the claims.

New claims 58-68 have been added. Support for the new claims can be found throughout the specification as filed, including particularly in the claims as originally filed (see e.g., original claims 1, 2, and 7). Additional support can be found in Example 1 (VASA and DAZL antigens comprising SEQ ID NOs: 3, 4, 7 and 8); Table 2 (immunization with plural antigens in Birds 548, 550, 552, 554, 556, and 566); Example 3 (repopulating recipient avians with donor PGCs); at page 4, lines 24-27 (intra- and interspecific donor PGCs); and at page 4, lines 27-28 (incubating a recipient embryo to hatch). As such, no new matter has been added by the inclusion of the new claims.

Reconsideration of the application as amended and in view of the remarks presented hereinbelow is respectfully requested.

<u>II.</u> Response to the Enablement Rejection

Claims 1-4 and 7-10 have been rejected under 35 U.S.C. § 112, first paragraph, upon the contention that the specification does not enable the full scope of the claims. After careful consideration of the rejection and the Patent Office's basis therefor, applicants respectfully traverse the rejection and submit the following remarks.

In support of the instant rejection, the Patent Office presents five general assertions that it alleges support the instant rejection. These five general assertions can be summarized as follows:

- (1) the specification fails to provide an enabled use for merely decreasing PGCs without producing a chimeric avian;
- (2) the specification fails to teach how to determine whether amounts of antigens or antibodies that decrease endogenous PGCs had been injected or obtained without sacrificing the embryo;
- (3) the specification does not enable repopulating an avian embryo with PGCs from another avian species;
- (4) the specification does not enable repopulating an avian embryo with PGCs from the same strain of avian; and
- (5) the specification does not enable using any antigen "associated with" PGCs as broadly claimed.

Turning first to Assertion (1), the Patent Office asserts that the sole disclosed use for decreasing PGCs in an avian embryo is to repopulate the embryo with donor PGCs to make a chimeric avian, and thus chimera formation is an essential step in the method.

Applicants respectfully disagree. Particularly, applicants respectfully submit that the Patent Office has focused on the wrong inquiry in assessing the enablement of the pending claims. Rather than consider whether the <u>product</u> of the claimed method has an enabled use, the Patent Office should be examining the claims to determine whether the <u>claimed methods per se</u> have an enabled use. Applicants respectfully submit that the claimed methods clearly do have an enabled use (*i.e.*, the production of a PGC-depleted avian embryo), which the Patent Office <u>in fact concedes is an enabled use of</u> the methods.

To elaborate, methods of claims 1 and 7 relate to the use of antibodies that bind to antigens associated with primordial germ cells to modulate the development of primordial germ cells (PGCs) during embryogenesis in avians or the number of PGCs in avian embryos. As a result, if the embryos produced by practicing the claimed methods

have a use, then it is believed to be axiomatic that <u>the claimed methods for producing</u> said embryos themselves have an enabled use.

Stated another way, the methods of claims 1 and 7 can be used to generate PGC-depleted embryos that can be employed as a starting point for creating chimeric avians. As such, the PGC-depleted avian embryos produced by the methods of claims 1 and 7 are analogous to chemical intermediates. Under current U.S. law, methods for producing chemical intermediates are clearly patentable subject matter. For example, the Patent Office's attention is directed to U.S. Patent Nos. 6,951,955 and 7,078,572, which claim *inter alia* methods for the synthesis of intermediates useful for the synthesis of tubulin inhibitors. As set forth in these two related patents, the claims are directed to methods for producing certain aldehydes. The aldehydes of Formula I disclosed therein have no disclosed utility other than as chemical intermediates for the synthesis of tubulin inhibitors. Nonetheless, two individual patents have issued with claims directed to processes of synthesizing these single use reagents.

Similarly, U.S. Patent No. 5,118,856 was the subject of *Eastman Chemical Co., v. BASF Aktiengesellschaft* 2000 WL 1897258 (E.D.Tenn.)). The '856 Patent claims methods for preparing cyclohexanedione derivatives, which the District Court found had no known use other than as chemical intermediates in the synthesis of certain herbicides (see FN1 of *Eastman Chemical Co.*). Similar to the patents discussed hereinabove, the claims of the '856 Patent recite methods for producing cyclohexanedione derivatives *per se*. Thus, applicants respectfully submit that it is clear that the fact that the cyclohexanedione derivatives can only be used for producing herbicides did not mean that the further step of synthesizing a herbicide was an essential step that needed to be recited in the claimed method.

Therefore, applicants respectfully submit that it is clear under U.S. law that claims to methods for producing an intermediate reagent can be patentable subject matter in the United States when the intermediate reagent is employable for producing a downstream composition with known utility. In the instant context, the intermediate reagent can be a PGC-depleted avian embryo, which can then be employed for producing a chimeric avian. As with the '955, '572, and '856 Patents, however, the steps that can be used for producing the downstream composition (e.g., the chimeric

avian), are not properly considered essential steps in the method for producing the intermediate reagent (e.g., the PGC-depleted avian embryo), and thus need not be recited in the claimed methods.

As a result, applicants respectfully submit that the Patent Office's apparent contention that using the intermediate (*i.e.*, the PGC-depleted embryo) for producing the end product (*i.e.*, a chimeric avian) would be an essential step under enablement analysis finds has not been supported in any authority, and thus is believed to be improper.

Accordingly, applicants respectfully submit that Assertion (1) above is not relevant to analysis under the enablement requirement of 35 U.S.C. § 112, first paragraph, and thus does not support the instant rejection.

Turning now to Assertion (2), the Patent Office asserts that the specification fails to teach how to determine whether amounts of antigens or antibodies that decrease endogenous PGCs had been injected or obtained without sacrificing the embryo. Applicants respectfully submit that this assertion also fails to support the instant rejection for <u>at least</u> the following reasons.

First, the experiments that are explicitly disclosed in the specification indicate that immunizing female avians with antigens associated with PGCs resulted in at least a 35% reduction in PGC numbers in the embryos. This was indeed determined by sacrificing the embryos, but applicants respectfully submit that once it is shown that immunizing the female avians predictably resulted in decreased PGC numbers, there would be no need to test each and every embryo for a similar result. The Patent Office has identified no reasonable scientific basis for its assertion that what was observed in the embryos disclosed in Example 2 of the instant specification would not also occur in other embryos that experienced the same treatment.

Continuing, it is noted that there is no requirement that the determination of a decrease in PGC number itself be performed on every single treated embryo or that it be performed exclusively *in ovo*. Rather, and as set forth in the previous response, the techniques disclosed for visualizing PGC numbers *in ovo* can be employed on a subset of treated animals, and the results of the tests performed on these avians can be extrapolated with a high degree of predictability to similar treated avians that are

permitted to hatch. Here as well, the Patent Office fails to base its assertion of unpredictability on any reasonable scientific foundation, and thus this assertion does not support the instant rejection.

Furthermore, the Patent Office's assertion that "[t]he ability to predict whether PGC numbers had decreased after immunizing an avian with an antigen was not described at the time of filing or in the specification; therefore, the ability to do so is 'unpredictable'" as set forth on page 6 of the Non-Final Official Action is believed to be incorrect. Applicants respectfully submit that Example 2 provides evidence that treatment predictably reduces PGCs as set forth in the following sections from page 56:

Immunizing females with individual peptides resulted in an approximately 35-55% reduction in endogenous PGC numbers, while immunization with two or more peptides simultaneously resulted in an approximately 55-70% reduction in endogenous PGCs.

Statistical analysis. Treatment differences for the average number of PGCs/embryo were analyzed using the GLM procedure of the SAS System (SAS Institute Inc., Cary, North Carolina, United States of America). The model was PGC = treatment hen. <u>Treatment differences were significant at p < .0002.</u> (emphasis added)

Applicants respectfully submit that a demonstration of highly significant differences between treated and untreated avians (p < 0.0002 would be understood by one of ordinary skill in the art to be <u>highly significant</u>) would show one of ordinary skill in the art that treatment <u>predictably</u> reduces PGC numbers. Thus, contrary to the Patent Office's assertion, the instant specification <u>does indeed</u> inform one of ordinary skill in the art that "[t]he ability to predict whether PGC numbers had decreased after immunizing an avian with an antigen" was predictable.

Additionally, applicants respectfully submit that after review of the instant specification, one of ordinary skill in the art would understand that a degree of germline chimerism (*i.e.*, the contribution of the donor PGCs to the recipient gonad) would be easily assayable by analyzing chimeric animals and/or by breeding the chimeras once they attain sexual maturity. Applicants respectfully submit that standard molecular biology techniques can be employed for assaying germline chimerism, and these assays can be performed on either interspecific chimeras or intraspecific chimeras.

To elaborate, routine techniques can be employed for isolating the terminal differentiated products of PGC differentiation (i.e., the eggs and sperm of chimeric avians). With respect to both interspecific and interspecific chimeras, routine genetic analysis can be employed to quantitate an extent of germline chimerism. another way, easily assayable genetic differences exist between species and among different members of the same species, and these can be exploited to assay germline The fact that these assays were not disclosed per se in the instant specification is irrelevant, since enablement analysis requires the Patent Office to consider what would have been within the routine ability of one of ordinary skill in the art (see M.P.E.P. § 2164.05(a), which states in part: "The specification need not disclose what is well-known to those skilled in the art and preferably omits that which is wellknown to those skilled and already available to the public. In re Buchner, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); Hybritech, Inc. v. Monoclonal Antibodies. Inc., 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987); and Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co., 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984)").

Additionally, applicants respectfully submit that one of ordinary skill in the art would also understand after review of the instant specification that standard breeding techniques could be employed to assay for germline chimerism. The Patent Office's assertion on page 7 of the Non-Final Official Action that the specification does not disclose a breeding assay that could be employed for this purpose. Applicants respectfully submit that here as well, there is no requirement that the specification teach what is already known to, or would be understood by, one of ordinary skill in the art. The techniques that would be required for assaying germline chimerism by breeding chimeras are all routine in the field of animal husbandry, and since one of the consequences of reducing endogenous PGCs is that germline chimerism is enhanced (see the instant specification at page 1, line 31 to page 2, line 1), applicants respectfully submit that routine breeding experiments can be employed to confirm the effect of the immunizations if for some reason it would be necessary.

Continuing, the Patent Office's assertions on pages 7 and 8 of the Non-Final Official Action that "the specification does not teach when the degree of chimerism

indicates a decrease in PGC numbers had been obtained", "applicants do not teach how to obtain a chimeric interspecies avian as encompassed by the claim, so those of skill would not be able to perform the assay when the donor PGCs were of a different species than the embryo", and "when the donor PGCs are the same species and strain as the recipient embryo, there is no "degree of chimerism" are all unsupported by any scientific reasoning and, in some instances, are factually inaccurate.

First, there is no requirement that a <u>specific degree of chimerism</u> be disclosed as evidence of a decrease in PGC numbers. The specification as filed indicates on page 1, line 31 to page 2, line 1, that chimerism can be increased by depleting endogenous PGCs. Routine comparisons can be employed to ensure that the treated embryos had reduced PGC numbers. The Patent Office has provided no reasonable scientific evidence to contradict the data explicitly set forth in the working examples of the instant specification that the methods of the pending claims successfully reduce PGC numbers and/or inhibit PGC development.

Second, and contrary to the Patent Office's assertion, the art <u>does indeed</u> teach how to produce interspecific chimeras, which is discussed in more detail hereinbelow. Given that different species have easily identifiable genetic differences, routine genetic analysis using molecular biological techniques can be employed to quantify germline chimerism.

And finally, applicants respectfully submit that the Patent Office's assertion that producing chimeras by administering donor PGCs from the same strain and species as a recipient would result in "no degree of chimerism" is factually and scientifically inaccurate. By definition, if any tissue in a recipient organism has been repopulated by even 1 cell that came from a donor organism, it is a chimera. Assaying a degree of chimerism might be somewhat more complicated when the donor and recipient are of the same species, but applicants respectfully submit that one of ordinary skill in the art would recognize that routine genetic assays could be employed to confirm chimerism since members of the same species are not genetically identical.

Therefore, applicants respectfully submit that Assertion (2) fails to support the instant rejection.

Turning now to Assertion (3), the Patent Office asserts that the specification does not enable repopulating an avian embryo with PGCs from another avian species. Applicants respectfully submit that the instant claims are directed towards reducing PGC numbers and/or inhibiting PGC development. Whether or not interspecific chimeras could be generated by transfer of PGCs from different species is thus <u>not relevant</u> to the instant analysis under the enablement provision of 35 U.S.C. § 112, first paragraph since the instant methods are not methods for producing chimeras.

Furthermore, applicants respectfully submit that the Patent Office has failed to consider what is disclosed in the specification in the context of what one of ordinary skill in the art would have known as of the instant filing date. Particularly, applicants respectfully submit that **Exhibits G**, **H**, and **I** filed with the response to the previous Official Action do indeed teach that interspecific chimeras can be produced by PGC transfer. **Exhibits G** and **H** teach that chicken/turkey chimeras and turkey/chicken chimeras could be produced by PGC transfer. **Exhibit I** teaches that germline chimeras could be produced by transferring pheasant PGCs into chicken embryos using standard techniques.

As such, applicants respectfully submit that the Patent Office has presented <u>no</u> <u>evidence</u> that the claimed techniques could not be employed to reduce PGC numbers or inhibit PGC development, and thus Assertion (3) does not support the instant rejection.

With respect to Assertion (4), this assertion is also based on what *might* be done with the products of practicing the instantly claimed methods. Here as well, the Patent Office's assertion is incorrect and fails to support the instant rejection.

To elaborate, the Patent Office asserts that the specification does not enable repopulating an avian embryo with PGCs from the same strain of avian. This assertion is believed to be flawed since there is no basis for concluding that there would be <u>any</u> unexpected barriers to repopulating an avian embryo with PGCs from the same strain of avian. Applicants respectfully submit that PGC repopulation experiments had been performed since at least 2002 (see references 1-4 of **Exhibit I** submitted previously). Therefore, applicants respectfully submit that in view of the state of the art as of the

instant filing date, repopulating an avian embryo with PGCs from the same strain of avian would have involved only routine experimentation.

As a result, the Patent Office's assertions that "specification and the art at the time of filing do not provide a use for such an embryo or for a viable avian obtained from such an embryo", "the specification and the art at the time of filing do not teach how to assay and determine PGC numbers decreased in such an embryo when they are repopulated with PGCs from the same species", and "[t]he specification and the art at the time of filing do not teach how to distinguish endogenous and donor PGCs when they are of the same strain of avian" on page 9 of the Non-Final Official Action fail to support the instant rejection. In each case, the assertions are factually inaccurate for the reasons set forth hereinabove (e.g., standard genetic assays could be employed for these purposes), and they relate to issues that are not relevant to enablement analysis of the instant claims.

Accordingly, applicants respectfully submit that Assertion (4) fails to support the instant rejection.

And finally, in Assertion (5) the Patent Office contends that the specification does not enable using any antigen "associated with" PGCs as broadly claimed. However, the Patent Office provides no reasoned scientific basis for this assertion. Instead, the Patent Office merely relies on speculation to contend that "[w]ithout using antigens that are specific to PGCs, the antibodies obtained in the egg would destroy all tissues expressing the antigen and prevent survival of the embryo" (see Non-Final Official Action at page 10).

Furthermore, the Patent Office fails to take into consideration that the specification as filed also discloses a series of exemplary antigens associated with primordial germs cells, which include, but are not limited to SSAE-1, ovomucin-like protein (OLP), Steel Factor (c-kit ligand), germ cell-less, dead end, VASA (including, but not limited to the chicken VASA homolog, CVH), DAZL, nanos, stella, and fragilis polypeptides (see specification at page 12, lines 5-8). Given that the instant claims must be view from the perspective of one of ordinary skill in the art after review of the instant specification, applicants respectfully submit that one of ordinary skill in the art

would also understand which antigens would represent appropriate antigens for use in the instantly claimed methods.

Therefore, even assuming *arguendo* that certain antigens might be undesirable for use in the instant methods, applicants respectfully submit that one of ordinary skill in the art would understand which antigens would in fact be expected to be useful in the instant claims, the Patent Office has not presented a *prima facie* case of lack of enablement based on the fact that certain embodiments that fall within the scope of the claim might be inoperative. This is set forth in M.P.E.P. § 2164.08(b), which states in part:

The presence of inoperative embodiments within the scope of a claim does not necessarily render a claim nonenabled. The standard is whether a skilled person could determine which embodiments that were conceived, but not yet made, would be inoperative or operative with expenditure of no more effort than is normally required in the art. *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1577, 224 USPQ 409, 414 (Fed. Cir. 1984)

Since applicants respectfully submit that with respect to antigens associated with PGCs, one of ordinary skill in the art "could determine which embodiments that were conceived, but not yet made, would be inoperative or operative with expenditure of no more effort than is normally required in the art", the Patent Office's assertion with respect to this point does not support the instant rejection.

Summarily, the Patent Office has employed an improper analysis in assessing the compliance of the instant claims with the enablement requirement of 35 U.S.C. § 112, first paragraph. None of the assertions presented in the Non-Final Official Action establishes a *prima facie* case of non-enablement of claims 1 and 7, and thus applicants respectfully request that the instant rejection be withdrawn at this time. Applicants further respectfully submit that claims 2-4 and 8-10 all depend from one of claims 1 and 7, and thus it is also believed that a *prima facie* case of non-enablement of these claims has not been presented.

As a result, applicants respectfully request that the instant rejection of claims 1-4 and 7-10 be withdrawn, and further that these claims be allowed at this time.

III. Response to the Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 1-4 and 7-10 have been rejected under 35 U.S.C. § 112, second paragraph, upon the contention that certain phrases appearing in the claims render the claims indefinite. Particularly, the Patent Office has asserted that the phrases "sufficiently high concentration of antibodies specific for the antigen to modulate the numbers [or development] of endogenous PGCs in an avian embryo" and "specific for the antigen to decrease endogenous PGC numbers" in claims 1 and 7 are unclear.

After careful consideration of the rejections and the Patent Office's bases therefor, applicants respectfully traverse the rejections and submit the following remarks.

III.A. Response to the First Rejection

According to the Patent Office, the metes and bounds of what applicants consider "sufficiently high concentration of antibodies specific for the antigen to decrease the PGC numbers [or development] in an avian embryo" (claims 1 and 7) remain unclear. The Patent Office contends that the specification does not teach how to determine whether PGC numbers decrease without sacrificing the avian, that the concentration of antibodies required to decrease the number or development of PGCs and maintain a viable embryo is not set forth in the specification or the art at the time of filling, and that the specification does not provide an assay for those of skill to determine when the amounts of antibodies were "sufficiently high" enough to decrease PGC numbers in an embryo that becomes a viable avian.

Applicants respectfully submit that these assertions are both inaccurate as well as irrelevant to the instant rejection.

To elaborate, the Patent Office first contends that the specification does not teach how to determine whether PGC numbers decrease without sacrificing the avian. While this assertion has been addressed in more detail hereinabove, applicants respectfully submit that whether or not the specification *per se* teaches how to do this, one of ordinary skill in the art would know several methods for accomplishing this goal. Therefore, one of ordinary skill in the art would easily be able to identify when a sufficiently high concentration of antibodies specific for the antigen to decrease the PGC

numbers [or development] in an avian embryo had occurred based on the guidance provided in the instant specification.

Next, the Patent Office asserts that the concentration of antibodies required to decrease the number or development of PGCs and maintain a viable embryo is not set forth in the specification or the art at the time of filing. This apparent requirement that a specific concentration be recited in the specification is believed to be clearly improper. Rather, applicants respectfully submit that all that is necessary is that one of ordinary skill in the art understand how to practice the methods of claims 1 and 7 and understand when the methods of claims 1 and 7 have been successfully executed. Given that all of the techniques required to assess the successful completion of the methods would be apparent to one of ordinary skill in the art based on the guidance provided in the instant specification, the instant assertion fails to support a rejection under 35 U.S.C. § 112, second paragraph.

And finally, the Patent Office asserts that the specification does not provide an assay for those of skill to determine when the amounts of antibodies were "sufficiently high" enough to decrease PGC numbers in an embryo that becomes a viable avian. Applicants respectfully submit that the clause "in an embryo that becomes a viable avian" is not relevant to the analysis under 35 U.S.C. § 112, second paragraph, at least because there is no requirement in the claims that the embryo become a viable avian.

Irrespective of the above, applicants respectfully submit that they have provided ample guidance in the instant specification as filed such that one of ordinary skill in the art would in fact have known how to assess PGC decreases in an avian that had hatched, and thus for this additional reason, the instant assertion fails to support a rejection under 35 U.S.C. § 112, second paragraph.

Summarily, applicants respectfully submit that the phrase at issue is functional language that is perfectly acceptable under M.P.E.P. § 2173.01, which states in part:

Applicant may use functional language, alternative expressions, negative limitations, or any style of expression or format of claim which makes clear the boundaries of the subject matter for which protection is sought. As noted by the court in *In re Swinehart*, 439 F.2d 210, 160 USPQ 226 (CCPA 1971), a claim may not be rejected solely because of the type of language used to define the subject matter for which patent protection is sought.

Thus, the Patent Office has not presented a *prima facie* case of lack of compliance with 35 U.S.C. § 112, second paragraph of claims 1 and 7. Applicants further respectfully submit that claims 2-4 and 8-10 all depend from one of claims 1 and 7, and thus it is also believed that the instant rejection is inapplicable to these claims as well. As a result, applicants respectfully request that the instant rejection be withdrawn at this time.

IV.B. Response to the Second Rejection

The Patent Office has also rejected claims 1-4 and 7-10 under 35 U.S.C. § 112, second paragraph, on a second basis. According to the Patent Office, "[i]t cannot be determined how specific the antibodies must be to decrease endogenous PGC numbers", [t]he phrases 'to bind' and 'to thereby decrease endogenous PGC numbers' are intended uses that may not occur", and that "those of skill would not be able to determine whether antibodies that recognized any DAZL antigen, for example, was encompassed by the claim of if the phrase was limited to antibodies that are specific to a particular DAZL antigen, i.e. DAZL-C or DAZL-N. (see Non-Final Official Action at pages 12-13).

Applicants respectfully disagree. Initially, applicants respectfully note that claims 1 and 7 have been amended to recite *inter alia* that the methods comprise immunizing a female bird with an antigen associated with primordial germ cells selected from the group consisting of SSEA-1, VASA, EMA-1, germ cell-less, dead end, nanos, stella, fragilis, and DAZL, whereby an egg produced by the female bird comprises a sufficiently high concentration of antibodies that bind to the antigen expressed by an avian embryo present within the egg to thereby decrease endogenous PGC numbers in the avian embryo. Support for this amendment can be found throughout the specification as filed, including particularly at page 35, lines 13-19. As such, no new matter has been added by the amendments to claims 1 and 7.

With respect to the amended claims, applicants respectfully submit that one of ordinary skill in the art would understand the metes and bounds of the phrase "bind to the antigen expressed by an avian embryo present within the egg to thereby decrease endogenous PGC numbers in the avian embryo". Applicants further respectfully submit

that assays that can be used to assess when this happens would be understood by one of ordinary skill in the art after consideration of the instant specification.

As a result, applicants respectfully submit that claims 1 and 7 fully comply with the requirements of 35 U.S.C. § 112, second paragraph, as reflected in M.P.E.P. § 2173.02 ("the examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. 112, second paragraph, by providing clear warning to others as to what constitutes infringement of the patent"). Applicants further respectfully submit that claims 1-4 and 7-10 are in condition for allowance, and respectfully solicit a Notice of Allowance to that effect.

V. <u>Discussion of the New Claims</u>

New claims 58-68 have been added. Support for the new claims can be found throughout the specification as filed, including particularly in the claims as originally filed (see e.g., original claims 1, 2, and 7). Additional support can be found in Example 1 (VASA and DAZL antigens comprising SEQ ID NOs: 3, 4, 7 and 8); Table 2 (immunization with plural antigens in Birds 548, 550, 552, 554, 556, and 566); Example 3 (repopulating recipient avians with donor PGCs); at page 4, lines 24-27 (intra- and interspecific donor PGCs); and at page 4, lines 27-28 (incubating a recipient embryo to hatch). As such, no new matter has been added by the inclusion of the new claims.

Applicants respectfully submit that new claims 58-68 are believed to be in condition for allowance for <u>at least</u> the reasons set forth hereinabove with respect to the instantly pending claims.

As a result, applicants respectfully submit that claims 1-, 8-10, and 58-68 are in condition for allowance, and respectfully solicit a Notice of Allowance to that effect.

CONCLUSIONS

Should there be any minor issues outstanding in this matter, the Examiner is respectfully requested to telephone the undersigned attorney. Early passage of the subject application to issue is earnestly solicited.

Application Serial No.: 10/541,947

DEPOSIT ACCOUNT

The Commissioner is hereby authorized to charge any fees associated with the filing of this correspondence to Deposit Account Number **50-0426**.

Respectfully submitted,

JENKINS, WILSON, TAYLOR & HUNT, P.A.

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